

## REMARKS

### *Status of the Claims*

Claim 1 is presently amended. Claims 2-4 and 7-8 were previously canceled. With entry of these amendments, claims 1 and 5-6 are currently pending and under consideration.

Applicants have amended claim 1 to recite “performing at least two of” options a), b) and c) for determining the amount of nucleic acid in relation to a first and second predetermined cut-off value. This amendment clarifies the description of the steps to be taken to determine the relationship of the amount of nucleic acid to the predetermined cut off values. No new matter is added by this amendment. Support for this amendment can be found throughout the specification as filed, for example on page 9.

Other minor amendments to claim 1 were made to clarify the claim language and structure. No new matter is added by these amendments.

### *Claim Rejections – 35 USC §112*

The Examiner has rejected claims 1 and 5-6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner notes the typographical error in line 7 of claim 1. (Action page 3)

Applicants regret the error and have amended claim 1 to delete “the” from the phrase. Applicants respectfully request withdrawal of the 112 rejections.

### *Claim Rejections – 35 USC §103*

The Examiner has rejected claims 1 and 5-6 under 35 U.S.C. 103(a) as being unpatentable over Cockerill et al. in view of Tyrell et al. (Action page 4) The Examiner asserts, in part, that in view of the teachings of Tyrell, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified Cockerill to arrive at the instant invention. (Action pages 5-6)

The Examiner notes (Action page 5) that the claims, prior to entry of the present amendments, recited the use of three different cutoff criteria only in the alternative; thus, the Examiner asserts that the teachings of Cockerill et al meet the requirements of the claims as written.

Solely to facilitate prosecution and without acquiescence in the rejections, Applicants have amended claim 1 to recite “performing at least two of” options a), b) and c) for determining the amount of nucleic acid in relation to a first and second predetermined cut-off value:

...performing at least two of:

- a) determining whether said amount of nucleic acid from said sample comprising the 16S/23S rDNA spacer region is above a first predetermined cut off value,
- b) determining whether said amount of nucleic acid from said sample comprising the 16S/23S rDNA spacer region is less than a second predetermined cut off value which is less than said first predetermined cut off value, and
- c) determining whether said amount of nucleic acid from said sample comprising the 16S/23S rDNA spacer region is less than said first predetermined cut off value and above said second predetermined cut off value, ...

*(amended claim 1, emphasis added)*

The Examiner asserts in part that Cockerill inherently discloses that positive signals must exceed a certain baseline level, and that this baseline value must be pre-determined prior to the comparison. (Action page 5). Applicants respectfully assert that Cockerill does not teach or provide suggestion of reference to a second predetermined cut off value as required by the claims as presently amended. Claim 1 as amended requires performing at least 2 determining steps and is not written in the alternative, thereby requiring that the amount of nucleic acid be compared to the second predetermined cut off value. Applicants direct the Examiner’s attention to page 9 lines 11-17 of the application as filed for discussion on the utility and importance of the second predetermined cut off value:

The second class of quantitative data can be subdivided into two subclasses by means of setting a second cut off value. Under these conditions, one class of data remaining under said second cut off value is clearly indicative for the absence of a pathogenic infection, the second class of data exceeding said second cut off value but remaining under said first cut off value represents those cases, where a pathogenic infection is not confirmed but on the other hand can also not be excluded.

Applicants assert that Cockerill does not teach detecting the presence of a bacterial pathogen utilizing a second predetermined cut off value. Tyrell does not provide teachings or suggestion relating to cut off values. Therefore, the combination of Cockerill and Tyrell does not provide all of the claim limitations as provided in the instant application. For the reasons stated above, Applicants respectfully assert that the Examiner has not established a *prima facie* case of obviousness and request withdrawal of the 103 rejections of claims 1 and 5-6.

## CONCLUSION


Applicants respectfully request entry of the present amendments and remarks. In view of the above, Applicants believe all claims now pending in this Application are in condition for allowance. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-730-8566.

Applicants respectfully request a 1-month extension of time to respond to the Office Action mailed September 18, 2008. The response date was December 18, 2008; with the granting of this request, the response time is re-set to January 21, 2009 (January 19-20 being Federal Holidays). The commissioner is hereby authorized to charge the amount of \$ 130, the fee due under 37 CFR §1.17(a)(1) to Deposit Account No. 50-0812. Please grant any additional extensions of time that may be required to enter this response and charge any additional fees or credit any overpayments to Deposit Account No. 50-0812.

Please direct all future correspondences to: Customer No. 22829.

Respectfully submitted,

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By:   
Rhea C. Nersesian  
Reg No. 55,488

Correspondence Address

Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
Pleasanton, CA 94588  
Tel: 925-730-8000  
Fax: 925-225-1128